

**§ 119.1 Dietary supplements containing ephedrine alkaloids.**

Dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use. Therefore, dietary supplements containing ephedrine alkaloids are adulterated under section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act.

[69 FR 6853, Feb. 11, 2004]

**PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS**

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AUTHORITY: 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 2421, 264.

SOURCE: 66 FR 6197, Jan. 19, 2001, unless otherwise noted.

**Subpart A—General Provisions**

**§ 120.1 Applicability.**

(a) Any juice sold as such or used as an ingredient in beverages shall be processed in accordance with the requirements of this part. Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible por-

tions of one or more fruits or vegetables, or any concentrates of such liquid or puree. The requirements of this part shall apply to any juice regardless of whether the juice, or any of its ingredients, is or has been shipped in interstate commerce (as defined in section 201(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(b)). Raw agricultural ingredients of juice are not subject to the requirements of this part. Processors should apply existing agency guidance to minimize microbial food safety hazards for fresh fruits and vegetables in handling raw agricultural products.

(b) The regulations in this part shall be effective January 22, 2002. However, by its terms, this part is not binding on small and very small businesses until the dates listed in paragraphs (b)(1) and (b)(2) of this section.

(1) For small businesses employing fewer than 500 persons the regulations in this part are binding on January 21, 2003.

(2) For very small businesses that have either total annual sales of less than \$500,000, or if their total annual sales are greater than \$500,000 but their total food sales are less than \$50,000; or the person claiming this exemption employed fewer than an average of 100 full-time equivalent employees and fewer than 100,000 units of juice were sold in the United States, the regulations are binding on January 20, 2004.

**§ 120.3 Definitions.**

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act, § 101.9(j)(18)(vi), and part 110 of this chapter are applicable to such terms when used in this part, except where redefined in this part. The following definitions shall also apply:

(a) *Cleaned* means washed with water of adequate sanitary quality.

(b) *Control* means to prevent, eliminate, or reduce.

(c) *Control measure* means any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard.

(d) *Critical control point* means a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.

(e) *Critical limit* means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.

(f) *Culled* means separation of damaged fruit from undamaged fruit. For processors of citrus juices using treatments to fruit surfaces to comply with § 120.24, *culled* means undamaged, tree-picked fruit that is U.S. Department of Agriculture choice or higher quality.

(g) *Food hazard* means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

(h) *Importer* means either the U.S. owner or consignee at the time of entry of a food product into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States. The importer is responsible for ensuring that goods being offered for entry into the United States are in compliance with all applicable laws. For the purposes of this definition, the importer is ordinarily not the custom house broker, the freight forwarder, the carrier, or the steamship representative.

(i) *Monitor* means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

(j)(1) *Processing* means activities that are directly related to the production of juice products.

(2) For purposes of this part, processing does not include:

(i) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing; and

(ii) The operation of a retail establishment.

(k) *Processor* means any person engaged in commercial, custom, or institutional processing of juice products, either in the United States or in a foreign country, including any person engaged in the processing of juice products that are intended for use in market or consumer tests.

(l) *Retail establishment* is an operation that provides juice directly to the consumers and does not include an establishment that sells or distributes juice to other business entities as well as directly to consumers. "Provides" includes storing, preparing, packaging, serving, and vending.

(m) *Shall* is used to state mandatory requirements.

(n) *Shelf-stable product* means a product that is hermetically sealed and, when stored at room temperature, should not demonstrate any microbial growth.

(o) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

(p) *Validation* means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified food hazards.

(q) *Verification* means those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

#### § 120.5 Current good manufacturing practice.

Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process juice are safe, and whether the food has been processed under sanitary conditions.

#### § 120.6 Sanitation standard operating procedures.

(a) *Sanitation controls*. Each processor shall have and implement a sanitation standard operating procedure (SSOP) that addresses sanitation conditions and practices before, during, and after processing. The SSOP shall address:

(1) Safety of the water that comes into contact with food or food contact surfaces or that is used in the manufacture of ice;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(3) Prevention of cross contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils,